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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,986	09/13/2006	Piero Del Soldato	026220-00061	6969

4372 7590 05/07/2007

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EXAMINER	
LAO, MARIALOUISA	
ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
05/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,986	DEL SOLDATO ET AL.	
	Examiner	Art Unit	
	MLouisa Lao, Ph.D.	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-23 are currently pending in the instant application and are subject to a lack of unity restriction requirement.

2. Priority
Receipt is acknowledged of Italy MI2002A001861 filed 8/29/2002, submitted under 35 U.S.C. §§ 119(a)-(d), which papers have been placed of record in the file.

3. Election/Restrictions

Restriction is required under 35 U.S.C. § 121 and § 372.

Claims 1-23 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

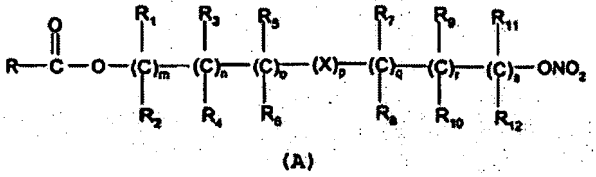
PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

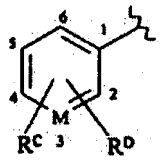
> Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.
>
> Annex B, Part 1 (e), provides combinations of different categories of claims and states:
> "The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:
> (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
> (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
> (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process .... "

This application contains the following illustrative inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1. Further due to numerous and widely divergent variables in the substituents of Formula A-F, for example: R1-R12, m-s, X and R, the process of preparing and the use thereof present in the claims, as recited, ***a precise listing of inventive sub-groups cannot be made.***

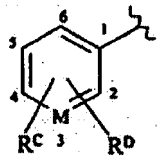
The following sub-groups are exemplary *only for Formula A*:



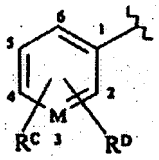
(A)



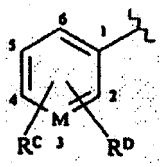
Group I: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = O



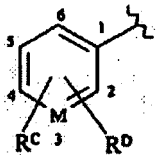
Group II: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = S.



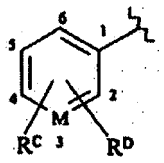
Group III: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = SO



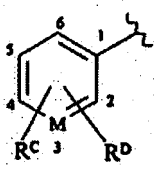
Group IV: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = SO2



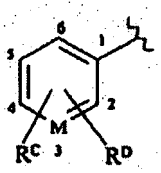
Group V: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = NR13 and R13 =H



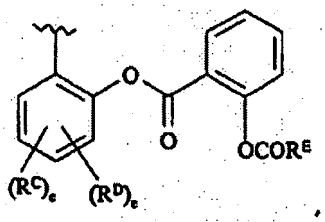
Group VI: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = NR13 and R13=C1-6 alkyl.



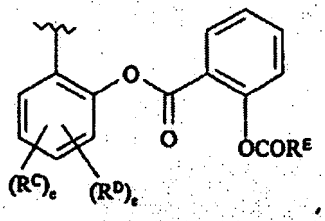
Group V: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = PR13 and R13 =H



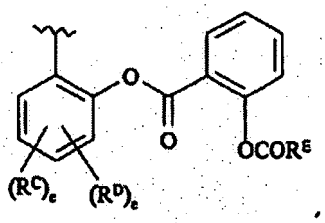
Group VI: when m-s are 0, i.e. not present, R= (I) , which is a radical of a pharmacologically active compound of Formula I from the instant specification , and X = PR13 and R13=C1-6 alkyl.



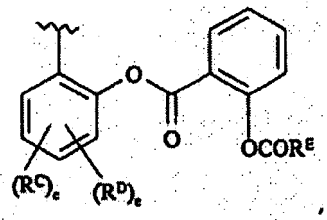
Group VII: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = O



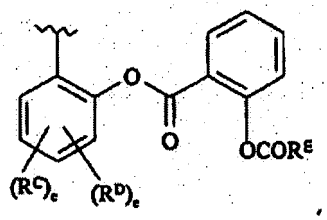
Group VIII: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = S.



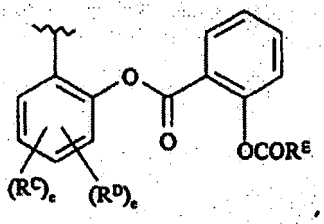
Group IX: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = SO



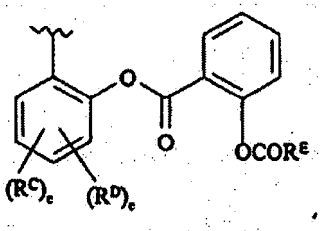
Group X: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = SO2



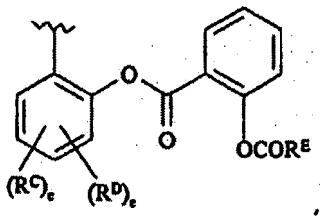
Group XI: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = NR13 and R13 =H



Group XII: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = NR13 and R13=C1-6 alkyl.



Group XIII: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = PR13 and R13 =H



Group XIV: when m-s are 0, i.e. not present, R= (II) , which is a radical of a pharmacologically active compound of Formula II from the instant specification , and X = PR13 and R13=C1-6 alkyl.

In accordance with 37 CFR § 1.499, applicant is required, in reply to this action, to elect a single disclosed species (and/or sub-group) to which the claims must be restricted. Again, this is ***not an exhaustive list***, as it would be impossible to produce such a list under the time constraints due to the large volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single disclosed species (and/or sub-group) in conjunction with the elected invention (a product and a method of use) by identifying another specific embodiment, i.e. a value for each substituent etc. not listed in the exemplary groups of the invention and Examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) the exemplary sub-groups shown above lack unity of invention since, under 37 CFR 1.475:

> Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to such subgroups is lacking.

The variables affect the structural core such that the core represents a plethora of compounds; which are patentably distinct and require separate search considerations.

Therefore, Claims 1-23 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on the search and examination of the claimed subject matter. Illustratively, a search on the compounds of formula A, with the various substituents, would mean numerous permutations.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule] 3.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a process for a product.

Furthermore, with respect to exemplary groups above, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

A product and a process specially adapted for the manufacture of said product; or
A product and process of use of said product; or
A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
A process and an apparatus or means specially designed for carrying out the said process; or
A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

> If an application contains claims to more or less that one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e),

> The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, since the variables represent the substituents, which result in a plethora of compounds and products defined by such sub-groups thereto, which are distinct inventions and require different searches, examinations and classifications. Therefore, the claims lack unity of invention and applicant is required to elect a single invention.

2. A telephone call was not made to applicants' agent to request an oral election to the above restriction requirement, due to the complexity of the art. MPEP § 812.01

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao, Ph.D. whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Fridays from 8:30am to 5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MLouisa Lao, Ph.D.
Examiner
Art Unit 1621

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SUPERVISORY PATENT EXAMINER
TC1600 GAU 1621